DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

New Star Lasers, Inc.
% Ms. Natalie R. Vollrath
Quality Assurance Manager
9085 Foothills Boulevard
Roseville, California 95747

APR 10 2008

Re: K080163
Trade/Device Name: CoolTouch LC215/CoolLipo Nd:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 22, 2008
Received: January 23, 2008

Dear Ms. Vollrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080163

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510(k) Number

Device Name	CoolTouch LC215/CoolLipo Nd:YAG Laser System
Indications for Use	In addition to previously cleared indications for use, the CoolTouch Model LC215/CoolLipo Nd:YAG Surgical Laser is indicated for laser-assisted lipolysis.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Appendix 2

510(k) Summary

Premarket Notification
510(k) Summary
(As Required by 21 CFR 807.93)

This 510(k) Summary of safety and effectiveness for the New Star Model CoolTouch LC215/CoolLipo Nd:YAG Surgical Laser systems is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Submitter:	New Star Lasers, Inc. d.b.a. CoolTouch, Inc.
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Natalie Vollrath Quality Assurance Manager
Telephone/Fax/Email:	(916) 677-1912 – Phone (916) 677-1901 – Fax nvollrath@newstarlasers.com - Email
Date prepared:	January 22, 2008
Device Trade Name:	CoolTouch LC215/CoolLipo Nd:YAG Surgical Laser
Common Name:	Nd: YAG Surgical Laser
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR §878.4810
Legally Marketed Predicate Devices:	CoolTouch NS160 CoolLipo Nd: YAG laser system (K072751) CoolTouch LC215 Nd:YAG laser system (K072424)
Device Description:	The CoolTouch LC215/CoolLipo Surgical Laser System is an Nd:YAG laser producing laser emission at 1320 nm. The laser consists of a cabinet which houses the power supply, the cooling system, microcontroller, laser, foot switch, and the fiber optic for delivery of the laser energy with microcannula setup.

Intended Use:	In addition to previously cleared indications, the Cooltouch LC215/CoolLipo is indicated for laser-assisted lipolysis.
Comparison:	The Cooltouch LC215/CoolLipo has the same principle of operation, the same wavelength and essentially the same pulse energy rate as the predicate devices.
Nonclinical Perfomance Data	None
Clinical Performance Data:	None
Conclusion:	The CoolTouch LC215/CoolLipo Nd:YAG Surgical Laser System is substantially equivalent to the predicate devices and is indicated for laser-assisted lipolysis.
Additional Information:	None requested at this time.